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MAY 31 2012

510(k) SUMMARY

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4368
Fax number	210-255-6727
Establishment Registration Number	1625774
Name of contact person	Shannon Scott, Regulatory Affairs Senior Manager
Date prepared	March 30, 2012
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C. Therapy System, ActiV.A.C., InfoV.A.C., V.A.C. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Classification panel	General and Plastic Surgery
Regulation	878.4780
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	Prevena Incision Management System (K100821)
Device description [21 CFR 807.92(a)(4)]	Negative pressure wound therapy system for application to surgically closed incisions.
Indications for use [21 CFR 807.92(a)(5)]	The ActiV.A.C., InfoV.A.C., V.A.C. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, they are also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Differences in intended use from the predicate(s)	The intended use for the subject devices has been expanded to include closed surgical incisions. This use is consistent with the indications for use cleared for the Prevena Incision Management System under 510(k) K100821.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]

The subject device was found to be equivalent to the predicate device in delivery of negative pressure to the indicated wound type. The devices are equivalent in terms of functional components.

Characteristic	**New Device** *V.A.C. Therapy Systems*	**Predicate** *Prevena™ Incision Management System* K100821
Indicated wound types	Chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps, grafts and surgical incisions.	Closed surgical incisions
Dressing	Multiple dressing components	Single, one size, multi-layer dressing.
Therapy unit	Multiple patient use; battery and AC powered	Single patient use only; battery powered

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

Non-clinical tests were not necessary to demonstrate substantial equivalence.

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

Clinical tests were not necessary to demonstrate substantial equivalence.

Conclusions drawn [21 CFR 807.92(b)(3)]

Equivalency testing of the V.A.C. Therapy Systems to the Prevena Incision Management System with respect to delivery of negative pressure wound therapy demonstrated that the systems are equivalent under all test conditions. The ActiV.A.C., InfoV.A.C., V.A.C. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are substantially equivalent to the Prevena Incision Management System (K100821) in terms of safety, function and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 3 1 2012

KCI USA, Inc.
% Ms. Shannon Scott
Regulatory Affairs Senior Manager
6203 Farinon Drive
San Antonio, Texas 78249

Re: K120033
Trade/Device Name: Activac Therapy Unit and Infovac Therapy Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered sunction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 25, 2012
Received: May 29, 2012

Dear Ms. Shannon Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Dep Clin Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120033

INDICATIONS FOR USE

510(k) Number (if known): **K120033**

Device Name: ActiV.A.C., InfoV.A.C., V.A.C. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems

Indications for Use:

The ActiV.A.C., InfoV.A.C., V.A.C. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings.

When used on open wounds, they are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, they are also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

(Posted November 13, 2003)

510(k) Number K120033